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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BRUTUS, JOEL F

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,490	Applicant(s) JOHANSSON ET AL.	
	Examiner JOEL F. BRUTUS	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-29, 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 1 and 17 are objected to because of the following informalities: After the ";", --and-- should have been followed right before the last paragraph. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 4-9, 13-16 depend on claim 3. There is insufficient antecedent basis for this limitation in the claim. Because claim 3 is cancelled. For purpose of examination, claim 4 is considered as if it depends from claim 1. Claims 5-9 and 13-16 are rejected because they depend on claim 4.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

Art Unit: 3768

to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 4-6, 8-11, 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richards-Kortum et al (US Pat: 6,370,422) in view of Irion et al (US Pat: 6,390,978) and further in view of Cane et al (Pub. No.: US 2001/0056237).

Regarding claims 1, and 31, Richards-Kotrum et al teach a light source 12 [see fig 1] The illumination light, or incident radiation 14, passes through a beam splitter 16 and is focused by a lens 22 to a point within the sample 20, which may be tissue that is pertinent to the device and the method as claimed. Since tissue is highly scattering, some of the illumination light 14 is reflected from all points illuminated within the sample 20. The light rays 18 reflected from the focal region of the lens may be refocused by the lens 22 and partially reflected by the beam splitter 16 to a point at the conjugate image plane. A majority of the light returning from the focal region in the tissue is passed to the detector 28 [see column 9 lines 41-55].

Richards-Kotrum et al teach the invention encompasses the design and development of a fiber optic confocal imaging system which uses reflected light to produce images of tissue with several micron resolutions. This system provides the user with images of the cellular structure and organization of the sampled tissue. This information can be used to determine the morphology (such as thickness, emphasis added) of tissue and its potential for diseases such as cancer [see column 4 lines 1-7].

Art Unit: 3768

The system is capable of imaging the entire thickness of the forearm epithelium and using 830 nm light [see column 2 lines 31-36]. Richards-Kotrum et al discuss a fiber optic design uses a fiber optic imaging bundle as a confocal image conduit between the endpiece optics and a confocal microscope. The function of the confocal microscope was to scan the illumination spot across the fiber bundle and to detect the emerging light. This arrangement does avoid the need for a mechanical translation system in the endpiece [see column 2 lines 51-57]. The presently disclosed methods and apparatus may be applied to the imaging of essentially sample, including any tissue in human or other animal. Such issues include bone, muscle, ligament, tendon, cartilage etc... [See column 9 lines 7-13]; using a wavelength range of 800 nm to 1100 nm [see column 12 lines 45-50].

Richards-Kotrum et al teach the invention is a confocal imaging apparatus for analyzing a sample including a radiation source, a scan system, a scan lens, a plurality of fibers, a distal index matching agent, a detector, and a coupling lens. The detector is in optical communication with the scan system and is configured to receive at least a portion of the secondary radiation and to produce a signal corresponding therewith [see column 4 lines 40-60]. A scan system 34 (that is used as a signal processor, emphasis added) illuminates each fiber in the bundle 38, the secondary radiation from each fiber is detected, and a signal is produced corresponding to the detected radiation. That signal may then be analyzed and processed as is known in the art to form an analysis, such as an image, of sample [see column 10 lines 55-65]. The

Art Unit: 3768

detector is known in the art to measure intensities of back scattered light (emphasis added).

Richards-Kottrum et al don't specifically mention measuring thickness of cartilage.

However, Richards-Kottrum et al do teach the system can assess morphology of tissue such as muscle, cartilage, and bone [see column 9 lines 7-13].

However, Irion et al teach an imaging method and a system for determining a physical or chemical condition of tissue in a human or animal body using at least one light beam is generated and split up into at least one measuring light beam and at least one reference light beam. The measuring light beam is injected along the same beam axis along which the ultrasonic pulse is injected into the tissue. The measuring light beam scattered back by the tissue is brought into an interference relationship with the reference light beam and is processed in optical image processing means [see abstract].

Irion et al further disclose physical condition in the meaning of the present invention is meant to describe, for example, geometrical parameters, such as the extension in space, the position in space, the thickness of the tissue (can be used to measure thickness of cartilage, emphasis added), as well as other physical variables, such as the density of the tissue under examination as a function of the locus. The method is, however, also simply used to describe the visual display of tissue in an image-display unit. The term chemical condition is used, for example, to describe the composition of the tissue [see column 1 lines 39-47].

However, Cane et al teach a processor to take signal proportional to the collagen concentration and to use signal as a measure of altitude to generate a relief map for display [see 0196]. Detector in N dimensional search space [see 0097]. Means provided for monitoring the intensity of the light remitted from a plurality of lines a two dimensional array of points [see 0150].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the above references by measuring the thickness of cartilage to see if the cartilage is degenerating; thereby prescribing the best possible treatment. One with ordinary skill in the art would be motivated to determine the thickness of tissue with measured intensities of backscattered reference light and measured light; for the purpose of providing an accurate diagnosis of a joint.

Regarding claims 4-6, 8-11, all other limitations are taught as set forth by the above combination. Richards-Kotrum et al disclose the same design has been implemented for reflection imaging using white light. The use of a white light source will limit the illumination power available to the system. The rationale given for using white light is eliminating the speckle observed when imaging a resolution test target with laser light [see column 2 lines 62-67].

Richards-Kotrum et al don't specifically teach comparing intensities of backscattered reference lights.

However, Cane et al teaches a comparator that may receive signals relating to the intensity of light [see 0197]. Proportion or intensity is controlled by control means to

Art Unit: 3768

spatial correlation of input images [see 0131]; Means provided for monitoring the intensity of the light remitted from a plurality of lines a two dimensional array of points [see 0150]; method of measuring the thickness of papillary dermis by shining infrared light at two wavelengths on area of the skin [see 0177]. Cane et al further teaches using white light [see 0128]. Detector in N dimensional search space [see 0097].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Cane et al reference with the above combination by using the comparator to compare intensity of back scattered lights from cartilage and/or bone as taught by Cane et al; for the purpose of analyzing the intensities for diagnosis purposes. An artisan would use a two dimensional intensity detector; for the purpose of increasing the system efficiency.

Regarding claims 13-16, all other limitations are taught as set forth by the above combination. Richards-Kotrum et al further teach wavelength in the NIR (near infrared region) and about 800 nm which less than 800 nm [see column 12 lines 52-56]. With a range of wavelengths and the invention is used for different components such as muscle, bone, cartilage, breast etc... as taught above; different absorptions between the components would show (emphasis added) because some of these component operate at different wavelengths.

6. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richards-Kortum et al (US Pat: 6,370,422) in view of Irion et al (US Pat: 6,390,978)

Art Unit: 3768

and further in view of Cane et al (Pub. No.: US 2001/0056237) as applied to claim 1, and 31 above and further in view of and further in view of Backman et al (US Pat: 6,624,890).

Regarding claim 17, all other limitations are taught as set forth by the above combination. Richards-Kotrum et al also teach the system can used polarized light and polarization control [see column 26 lines 1-5].

Richards-Kotrum et al don't exactly a polarizer to generate polarized and non-polarized light.

However, Backman et al further teaches a system that delivers collimated polarized light on tissue and separate two orthogonal polarizations of backscattered light [see column 5 lines 32-24]; fiber, lens, polarizer with linear polarization, a broadband polarizer linearly polarizes the beam [see column 5 lines 43- 46].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Richards-Kotrum et al reference with Backman et al reference by only using polarizer with linear polarization, a broadband polarizer linearly polarizes the beam [see column 5 lines 43- 46] as taught by Backman et al and controlling a polarization state; for the purpose of having the electric field vibrate in a single plane.

Regarding claims 18-21, 23-27, and 29, all other limitations are taught as set forth by the above combination.

Richards-Kotrum et al don't specifically teach polarized and non-polarized lights are extracted from white light.

However, Richards-Kotrum et al using white light and suggesting using polarization technique.

However, Backman et al teach polarizer with linear polarization, a broadband polarizer linearly polarizes the beam [see column 5 lines 43- 46]; polarizer and analyzer that can be placed at the tip of the probe [see column 8 lines 10-20].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to extract polarized and non-polarized lights from white light for polarization state; in order to eliminate speckle.

7. Claims 7, 12, 22, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richards-Kortum et al (US Pat: 6,370,422) in view of Irion et al (US Pat: 6,390,978) and further in view of Cane et al (Pub. No.: US 2001/0056237) as applied to claim 1, 17 and 31 above and further in view of Backman et al (US Pat: 6,624,890) and further in view of Kaneko et al (US Pat: 5,305,759).

Regarding claims 7, 12, 22, and 28, all other limitations are taught as set forth by the above combination.

The above combination doesn't teach multiplexing.

However, Kaneko et al teach multiplexing reflecting lights [see column 35 lines 30-40];

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references by using multiplexing; for the purpose of allowing multiple analog message signals or digital data streams to be combined into one signal over a shared medium; to reduce cost by sharing an expensive resource.

Response to Arguments

8. Applicant's arguments with respect to claims 1, 4-29 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that the previously used references don't teach measuring thickness of cartilage.

Richards-Kottrum et al teach the system can assess morphology of tissue such as muscle, cartilage, and bone [see column 9 lines 7-13]. The presently disclosed methods and apparatus may be applied to the imaging of essentially sample, including any tissue in human or other animal. Such issues include bone, muscle, ligament, tendon, cartilage etc... [See column 9 lines 7-13].

However, Irion et al further disclose physical condition in the meaning of the present invention is meant to describe, for example, geometrical parameters, such as the extension in space, the position in space, the thickness of the tissue (can be used to measure thickness of cartilage, emphasis added), as well as other physical variables, such as the density of the tissue under examination as a function of the locus. The method is, however, also simply used to describe the visual display of

Art Unit: 3768

tissue in an image-display unit. The term chemical condition is used, for example, to describe the composition of the tissue [see column 1 lines 39-47].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the above references by measuring the thickness of cartilage to see if the cartilage is degenerating; thereby prescribing the best possible treatment. One with ordinary skill in the art would be motivated to determine the thickness of tissue with measured intensities of backscattered reference light and measured light; for the purpose of providing an accurate diagnosis of a joint.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3768

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768